

Nuclear Safety Rules Quality Assurance

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EH-10**

Quality Assurance

QA Rule Structure

- Main Body
- Subpart A (QA Requirements)
- Subpart B (Safety Basis Requirements)

Quality Assurance: Main Body

Scope

- Applicable to DOE contractors, DOE personnel and others that affect or may affect safety at DOE nuclear facilities

Quality Assurance: Main Body

Exclusions

- Activities regulated by the NRC
- Activities conducted by Navel Nuclear Propulsion
- Transportation activities regulated by DOT
- Activities conducted under NWPA
- Launch of nuclear energy system into space

Quality Assurance: Main Body

Definitions

- See the rule

Quality Assurance: Main Body

- General Requirements
- Contractor actions must be consistent with the rule
- Contractor must implement the rule
- Must be implemented to assure protection of workers, public and environment
- If GOGO, DOE must assure compliance

Quality Assurance: Main Body

Enforcement

- Rule requirements are subject to enforcement in accordance with 10 CFR 820

Quality Assurance: Main Body

Recordkeeping

- Contractor must maintain records to substantiate compliance with the rule

Quality Assurance: Main Body

Graded Approach

- Contractor must use a graded approach in implementing the rule and document basis
- Graded approach aligns the level of quality related controls with the safety significance of the item or activity

Quality Assurance: Subpart A

Scope

- Subpart A establishes QA requirements for contractors conducting activities, including providing items and services that affect or may affect, nuclear safety of DOE nuclear facilities

Quality Assurance: Subpart A

Scope (*continued*)

- Nuclear facility is to include hazard category 1, 2, and 3 nuclear facilities and “below category 3” nuclear facilities

Quality Assurance: Subpart A

Scope (*continued*)

- QA rule applies to activities/events that lead to radiological consequences
 - Work Processes
 - Quality Improvement

Quality Assurance: Subpart A

Scope (*continued*)

- The following are activities *not* within the scope of the rule:
 - Accelerators, check or calibration sources, electron microscopes, X-ray machines

Quality Assurance: Subpart A

Scope (*continued*)

- EGS 00-03
(Specific Issues on Applicability of Subpart A)
 - *Not* limited to SAR and TSR content
 - *Not* limited to work involving physical activity
 - *Not* limited to work handling radioactive material
 - *Not* limited to only those facilities where nuclear material is present

Quality Assurance: Subpart A

Quality Assurance Program

- Contractor for DOE nuclear facility must:
 - Submit a QAP to DOE for approval
 - Modify the QAP as directed by DOE
 - Annually submit any changes to the QAP
 - Conduct work in accordance with the QAP

Quality Assurance: Subpart A

Quality Assurance Plan (*continued*)

- The QAP must:
 - Describe how the QA criteria are satisfied
 - Integrate QA criteria with SMS
 - Use consensus standards in QAP development and implementation
 - Describe how subcontractors satisfy the QA criteria

QA Elements - Management

- Describe the management controls for all aspects of facility operations
- Conduct initial and continued training for personnel qualification
- Implement corrective action processes to improve the quality of operations
- Maintain controlled documents and records

QA Elements - Performance

- Perform work and maintain equipment using established procedures and standards
- Control and verify designs to applicable design bases
- Control procured items and services
- Inspect and test to established criteria

QA Elements - Assessment

- Management self-assess their processes and resolve identified problems
- Perform independent assessments of item and activity quality to promote improvement

Quality Assurance: Subpart B

Scope

- Subpart B (Safety Basis Requirements) is only applicable to hazard category 1, 2, and 3 DOE nuclear facilities

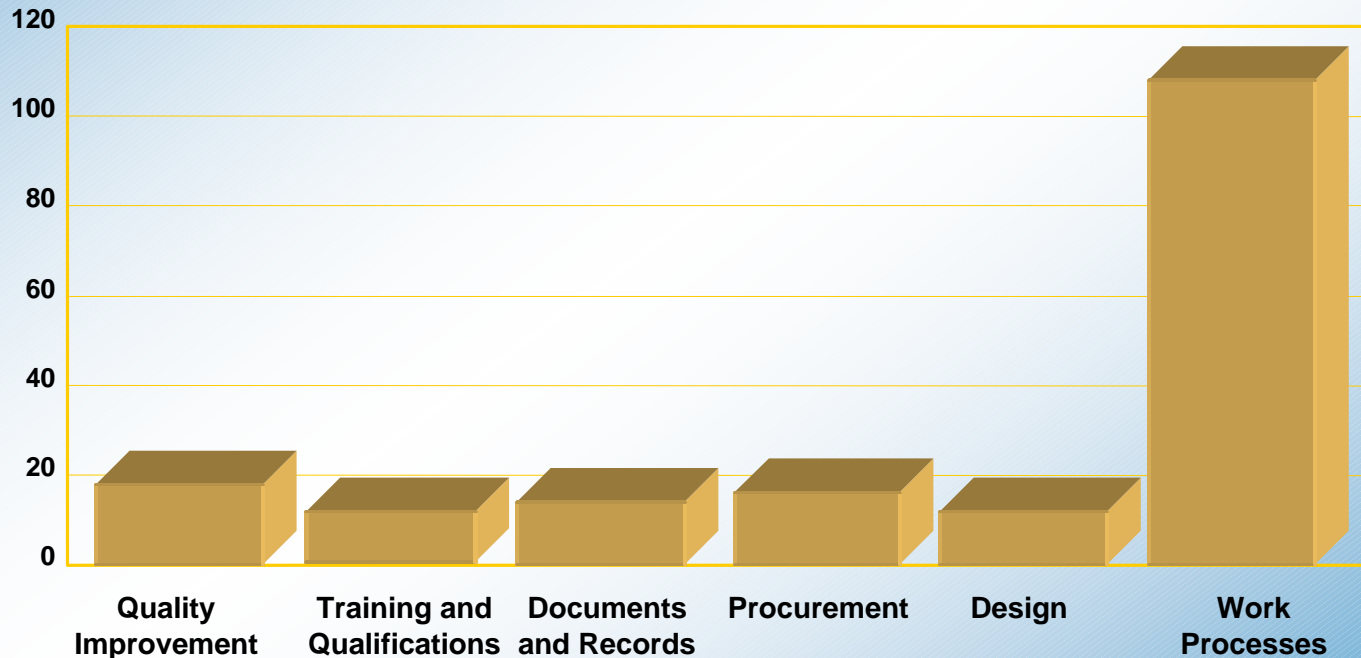
Quality Assurance: Subpart B

General

- Adds requirements for the following:
 - Safety Analysis Reports (SAR)
 - Technical Safety Requirements (TSR)
 - Unreviewed Safety Question (USQ) process

Quality Assurance

Quality Assurance Rule



Major 1999 Noncompliances Reported into NTS